

PUBLISHED

UNITED STATES COURT OF APPEALS

FOR THE FOURTH CIRCUIT

CATHERINE W. GRIFFIN,

Plaintiff-Appellant,

v.

No. 94-1219

MEDTRONIC, INCORPORATED,

Defendant-Appellee.

Appeal from the United States District Court
for the District of Maryland, at Baltimore.
Frederick N. Smalkin, District Judge.
(CA-93-60-S)

Argued: September 27, 1994

Decided: April 30, 1996

Before WIDENER and MOTZ, Circuit Judges, and MICHAEL,
Senior United States District Judge for the Western District of
Virginia, sitting by designation.

Affirmed by published opinion. Senior Judge Michael wrote the opinion, in which Judge Widener and Judge Motz joined.

COUNSEL

ARGUED: Kristen Atkins Brinster, SEIDENMAN, SUTHERLAND & LYNN, P.A., Baltimore, Maryland, for Appellant. Harley Thomas Howell, Benjamin Rader Goertemiller, HOWELL, GATELY, WHITNEY & CARTER, Towson, Maryland, for Appellee. **ON BRIEF:** Jerome J. Seidenman, John R. Sutherland, SEIDENMAN, SUTHER-

LAND & LYNN, P.A., Baltimore, Maryland, for Appellant. John S. Bainbridge, Jr., HOWELL, GATELY, WHITNEY & CARTER, Towson, Maryland, for Appellee.

OPINION

MICHAEL, Senior District Judge:

Catherine Griffin appeals the decision of the district court granting summary judgment to Medtronic, Inc. ("Medtronic") on the grounds that Griffin's claims are preempted by 21 U.S.C.A. § 360k (West Supp. 1995), enacted as part of the Medical Device Amendments of 1976 (MDA) to the Federal Food, Drug, and Cosmetic Act. On the recent authority of Duvall v. Bristol-Myers-Squibb Co., 65 F.3d 392 (4th Cir. 1995), we affirm in part, reverse in part and remand.

I.

In 1984, a pacemaker, manufactured and sold by Medtronic, was implanted in Griffin's chest to help regulate and control her heart rate. The pacemaker consisted of a dual chamber generator and polyurethane leads. In 1986, the pacemaker failed and was removed. However, portions of the leads remained in Griffin's chest. Griffin's physicians inserted a new Medtronic pacemaker which ultimately failed in 1989. Doctors removed most of the second pacemaker, but once again, portions of the leads remained in Griffin's chest. Griffin then received yet another Medtronic pacemaker which has not functioned properly to date, allegedly because of the remnants of the leads left in Griffin's chest.

In 1992, Griffin brought the current suit against Medtronic in Maryland state court. Her complaint states five counts: (1) negligent design and manufacture; (2) breach of express warranty; (3) breach of an implied warranty of fitness for a particular purpose; (4) strict liability for defective manufacture; and (5) intentional misrepresentation of the defective condition of the pacemakers. Medtronic removed the case to federal court on the basis of diversity of citizenship.

The district court, relying on the authority of Stamps v. Collagen Corp., 984 F.2d 1416 (5th Cir. 1993), and King v. Collagen Corp., 983 F.2d 1130 (1st Cir. 1993), ruled that Griffin's claims were preempted by § 360k of the MDA¹ and, accordingly, granted Medtronic's motion for summary judgment. No material facts are in dispute. The appeal presents questions of law subject to de novo review. Higgins v. E.I. DuPont de Nemours & Co., 863 F.2d 1162, 1166-1167 (4th Cir. 1988).

II.

A.

The preemption issues presented by this appeal are controlled by our recent decision in Duvall v. Bristol-Myers-Squibb Co., 65 F.3d 392 (4th Cir. 1995). The plaintiff in Duvall brought several state-law claims against the manufacturer of a penile prosthesis after undergoing surgery to implant the prosthesis.² In ruling that the majority of

¹ Subject to a possible exemption not claimed here, section 360k provides that:

[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement --

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C.A. § 360k.

² Under the framework of the MDA, penile inflatable implants are classified as "Class III" medical devices, and as such, are subject to the most rigorous regulation. Duvall, 65 F.3d at 396; 21 C.F.R. § 876.3350 (1995). A manufacturer must generally receive approval from the Food and Drug Administration ("FDA") before marketing a Class III device. However, the prosthesis was brought to market via the "substantially equivalent" mechanism outlined at 21 C.F.R. § 807.100(a) (1995). Id. Under this administrative regime, a Class III device for which the FDA does not yet require the usual premarket approval may be marketed if the

plaintiff's claims were preempted by § 360k, we held that "state-law claims are preempted by § 360k to the extent that, if successful, such claims would impose requirements under state law different from or in addition to requirements applicable to a device under the MDA." Id. at 398. With this language as a baseline, we concluded that plaintiff's breach of implied warranty, strict liability, and negligence claims were necessarily preempted by § 360k. However, we held with respect to plaintiff's breach of express warranty claim that "although § 360k preempts express warranty claims to the extent that they are based on FDA-mandated labeling, packaging, and advertising, it does not preempt an express warranty claim that is based on a manufacturer's voluntarily-made representations regarding its product." Id. at 400-401. We therefore reversed and remanded, for further consideration in light of that holding, the district court's grant of summary judgment for Medtronic on the express warranty claim.

B.

Given the authority of Duvall, we deal only briefly with Griffin's arguments.³ Griffin's breach of implied warranty, strict liability, and negligence claims are preempted by § 360k because were Griffin to prevail on those claims, Medtronic would be burdened with requirements different from or in addition to those applicable to pacemakers under the MDA. As did the plaintiff in Duvall, Griffin here argues that these state-law claims, if successful, would not impose any different or additional requirements on Medtronic because the MDA does not impose specific requirements on pacemakers in the first instance. However, we held in Duvall that the premarket notification procedure under the MDA, codified at 21 C.F.R. § 807.87 (1995) and known as 510(k) Notification, constitutes a requirement applicable to devices under the MDA because the notification procedure requires a manu-

manufacturer shows that the device is "substantially equivalent" to a device marketed before the effective date of the MDA. Id. The pacemakers at issue in this case are also Class III medical devices, 21 C.F.R. § 870.3610 (1995), brought to market under the authority of the "substantially equivalent" process.

³ In fairness to Griffin, we note that argument was heard on Griffin's appeal before Duvall was decided.

facturer to submit to the FDA, among other things, certain descriptive particulars, such as proposed labels and advertisements. Id. at 400 ("510(k) Notification is a requirement applicable to the device under the MDA"). Thus, successful state-law claims would indeed impose a requirement in addition to a requirement already imposed on pacemakers under the MDA. Accordingly, Griffin's breach of implied warranty, strict liability, and negligence claims are preempted by § 360k.

With respect to Griffin's express warranty claim, we must return the case to the district court to determine whether the claim is based on promises voluntarily made by Medtronic -- and therefore, not preempted by § 360k -- or whether it is based on FDA-mandated labeling, packaging, and advertising of Medtronic pacemakers -- and therefore preempted by § 360k.

III.

Griffin's complaint contains one count of intentional misrepresentation. This claim alleges that Medtronic did not disclose the fact that the pacemakers were defective and unsafe for human use. Although we were not presented with an intentional misrepresentation claim in Duvall, we believe the rationale of Duvall mandates that we affirm the decision of the district court granting summary judgment for Medtronic on that claim.

We reach this conclusion because the record in this case reveals no statements or other communications made to Griffin or to her physician that are any different from those made to the FDA. Thus, the premise of Griffin's intentional misrepresentation claim is that Medtronic had a duty to disclose information to Griffin and to her physician different from that which Medtronic provided to the FDA.⁴ If successful, this claim would result in the imposition of a require-

⁴ Of course, Griffin's claim might also be premised on the notion that Medtronic did not adequately comply with FDA disclosure requirements. However, the FDA alone is empowered to enforce its regulations. A private right of action seeking enforcement of FDA regulations has not been recognized. See, e.g., Rodriguez v. SK&F Co., 833 F.2d 8, 9 (1st Cir. 1987), and cases cited therein.

ment above and beyond those imposed by the MDA. Under Duvall, such state-law claims are preempted. Accordingly, we conclude that Griffin's intentional misrepresentation claim is preempted.

IV.

Under the authority of Duvall, we affirm the decision of the district court granting summary judgment for Medtronic on Griffin's negligence, breach of implied warranty, strict liability, and intentional misrepresentation claims. However, we reverse in part and remand the case with respect to Griffin's breach of express warranty claim for further proceedings not inconsistent with this opinion.

AFFIRMED IN PART; REVERSED
AND REMANDED IN PART